DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#22

Food and Drug Administration
Rockville MD 20857

Re: Lamisil Cream
Docket No. 93E-0147

MAY 11 1993

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RECEIVED

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the application for patent term extension for U.S. Patent No. 4,755,534, filed by Sandoz, Ltd., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lamisil Cream, the human drug product claimed by the patent.

The total length of the review period for Lamisil Cream is 3,464 days. Of this time, 2,917 days occurred during the testing phase and 547 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 9, 1983.

   The applicant claims June 6, 1983, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 9, 1983, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: July 3, 1991.

   The applicant claims June 30, 1991, as the date the new drug application (NDA) for Lamisil Cream was initially submitted. However, FDA records indicate that NDA 20-192 was initially submitted on July 3, 1991.

3. The date the application was approved: December 30, 1992.

   FDA has verified the applicant's claim that NDA 20-192 was approved on December 30, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Robert S. Honor
Patent and Trademark Affairs
Sandoz Pharmaceuticals Corporation
59 Route 10
E. Hanover, NJ 07936